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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/826,088

04/16/2004

Steven R. Christenson

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02/20/2008

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EXAMINER

AFZALI, SARANG

ART UNIT

PAPER NUMBER

3726

MAIL DATE

DELIVERY MODE

02/20/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/826,088	<b>Applicant(s)</b> CHRISTENSON ET AL.	
	<b>Examiner</b> SARANG AFZALI	<b>Art Unit</b> 3726	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 16-19 is/are rejected.
- 7) ☒ Claim(s) 9-15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20040719</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Species B, Fig. 10 in the reply filed on 12/10/2007 is acknowledged.

### ***Specification***

2. The disclosure is objected to because of the following informalities:  
Specification, line 1, add - - now US patent No. 6,743,204, - - after "2001," and before "which is".

Appropriate correction is required.<sup>1</sup>

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: A METHOD OF MANUFACTURING OF AN IMPLANTABLE DRUG INFUSION DEVICE WITH PERISTALTIC PUMP HAVING A RETRACTABLE ROLLER.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 4, 6, 8 and 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Lepp et al. (US 4,142,845).

As applied to claim 1, Lepp et al. teach a method of manufacture of an implantable drug infusion device comprising the steps of:

(a) assembling a race (29, Fig. 1) configured to support a pump tube (15, Fig. 3) along a path;

(b) assembling a roller assembly (38, Fig. 3) configured to apply pressure to the tube against the race at one or more points along the path, the roller assembly including at least one retracting roller (retracting rollers 39, Fig. 3);

(c) retracting the roller away from the race (Fig. 10, col. 6, lines 34-37); and

(d) inserting a pump tube (15, Fig. 3) between the retracted roller and the race.

As applied to claim 2, Lepp et al. teach a method further having the step of assembling a drive assembly (col. 4, lines 16-25).

As applied to claim 4, Lepp et al. teach a method further having the step of deretracting the roller by moving the roller towards the race, thereby allowing the roller to apply pressure to the tube against the race (Fig. 11).

As applied to claim 6, Lepp et al. teach a method wherein the step of assembling the roller assembly comprises assembling two or more retracting rollers (39, Fig. 3),

each retracting roller configured to apply pressure to the tube against the race, and the step of retracting comprises retracting each roller (Fig. 10).

As applied to claim 8, Lepp et al. teach a method wherein the step of retracting the roller away from the race further includes using a tool (disc 45, Fig. 10) to retract the roller.

As applied to claims 16-19, Lepp et al. teach a method wherein the steps of assembling the race and the roller assembly include the steps of assembling the race and the roller assembly within a pumphead assembly and a housing (col. 4, lines 16-25).

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 3, 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Troutner (EP 0 239 255) in view of Lepp.

As applied to claim 1, Troutner teaches a method of manufacture of an implantable drug infusion device comprising the steps of:

(a) assembling a race (212, Fig. 2) configured to support a pump tube (211, Fig. 2) along a path;

(b) assembling a roller assembly (203, Figs. 2 & 6) configured to apply pressure to the tube against the race at one or more points along the path, the roller assembly including at least one retracting roller (retracting rollers 604, Fig. 6).

However, Troutner does not explicitly teach the step of retracting a roller away from the race followed by inserting a pump tube between the retracted roller and the race.

Lepp et al. teach a method of manufacturing an implantable drug infusion device wherein a roller (39, Fig. 3) of a retractable roller assembly (38) is retracted away from the race (29) in order to insert a pump tube (15) between the retracted roller and the race (Fig. 10, col. 6, lines 34-37). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have provided the step of retracting the retractable roller followed by the insertion of the pump tube to the peristaltic pump of Troutner as taught by Lepp because it would have provided a more accessible assembly resulting in a more efficient manufacturing process.

As applied to claim 3, Troutner teaches a method wherein the step of retracting the roller away from the race further includes compressing a biasing member (spring 611, Fig. 6), that biases the roller towards the race.

As applied to claim 5, Troutner teaches a method further comprising the steps of: deretracting the roller by decompressing the biasing member; and allowing the roller to move towards the race so that the biasing member causes the roller to apply pressure to the tube (Left-hand roller 604 applying pressure on tube 211, Fig. 6).

As applied to claim 7, Troutner teaches a method wherein the step of assembling the roller assembly comprises assembling three or more retracting rollers (three rollers 604, Fig. 6), each retracting roller configured to apply pressure to the tube against the race, and the step of retracting comprises retracting each roller.

Note that each of the rollers (604, Fig. 6) is configured and thus capable of applying a pressure to the tube against the race and as such each of the rollers that is applying pressure to the tube at the time of retracting step is retracted.

### ***Allowable Subject Matter***

8. Claims 9-15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARANG AFZALI whose telephone number is (571)272-8412. The examiner can normally be reached on 7:00-3:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Bryant can be reached on 571-272-4526. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. A./  
Examiner, Art Unit 3726  
2/7/2008

/David P. Bryant/  
Supervisory Patent Examiner, Art Unit 3726